PERMIT TO CONSTRUCT ANALYSIS

FACILITY MAILING ADDRESS

Abbott Cardiovascular Systems, Inc.
26531 Ynez Road
Temecula, CA 92591

(ID: 45489 - TITLE V)

EQUIPMENT LOCATION

SAME AS ABOVE

EQUIPMENT DESCRIPTION

APPLICATION NO. 572699 - NEW CONSTRUCTION

STERILIZATION SYSTEM CONSISTING OF:

1. STERILIZER, NOXILIZER, MODEL RTS 360, 6'-6" L. X 6'-6" W. X 6'-6" H.
2. NO_2 CYLINDERS, 2 POUND CAPACITY.
3. INTEGRATED TWO STAGE SCRUBBER SYSTEM CONSISTING OF:
    A. THREE PRIMARY SCRUBBERS IN PARALLEL, EACH WITH 3.6 KG OF PURAFIL SP CHEMISORBANT MEDIA CONTAINING SODIUM PERMANGANATE.
    B. ONE SECONDARY SCRUBBER WITH TWO SECTIONS IN SERIES, EACH WITH 1 KG OF PURAFIL SP CHEMISORBENT MEDIA CONTAINING SODIUM PERMANGANATE.
    C. 1.6 HP EXHAUST FAN.

APPLICATION NO. 572701 - FACILITY PERMIT MODIFICATION

DE MINIMUS SIGNIFICANT TITLE V PERMIT REVISION

HISTORY

Application No. 572699 was filed on February 24, 2015, for a Class I Permit to Construct.
Application No. 572701 was filed on February 24, 2015, for a Title V Permit Revision.

The following compliance activity was found in District records (CLASS computer database) during the past 2 years.

Complaints: There were no complaints credited to this facility during the past 2 years.

Notices to Comply: There were no Notices to Comply issued to Abbott within the past 2 years.

Notices of Violation:

P61187, Violation date 10/04/13 for Failing to re-check NOx emissions on two natural gas boilers (P/Os G21362 and G21363) rated greater than 5mmbtu/hr within 72 hours from exceeding the NOx emission limit.
Applicant in compliance as of 10/28/13

PROCESS DESCRIPTION

Abbott Cardiovascular Systems, Inc. (Abbott) manufactures therapeutic medical devices for the treatment of atherosclerotic disease of the coronary and peripheral arteries. Devices made include angioplasty balloon catheters, guide wires, wire-mesh stents, and accessories.

EVALUATION

Abbott has proposed to install a sterilizer that uses Nitrogen Dioxide (NOx) as a sterilizing agent at room temperature.

PRODUCT INFORMATION –

The following technical information was provided as a Word Document by Noxilizer, Inc., the manufacturer of the proposed sterilizing unit. Also included are clarifications requested in e-mail dated 3-9-15:

1. Technology Description:

The RTS 360 is an approximate 730 liter cylindrical sterilizer with an inscribed rectangular sterilization envelop of approximately 360 liters. The RTS 360 is a self-contained, stand-alone sterilizer operating at ambient temperature. In the self-contained configuration, the RTS 360 service requirement is only a dedicated power supply. The RTS 360 system consists of hardware and firmware that monitors and controls the overall operation of the sterilizer. The R&D unit intended for Abbott Cardiovascular allows operator access to the software that controls the parameters for the sterilization cycles.

The sterilization cycle consists of one or more repeats (pulses) of the following software controlled actions: evacuation of the chamber, addition of gas into the chamber (NO_2 sterilant and humidity), and timed dwell without further addition of gas, followed by multiple air purges of the chamber (aeration) at the end of each sterilization cycle.

The RTS 360 uses nitrogen dioxide (NO_2) as the sterilant. The sterilant addition results in a small pressure increase within the sterilization chamber. The balance of the gas added is humidified air* which is added until the pressure in the sterilization chamber reaches the target pressure for the dwell phase. Humidity is added to the sterilization chamber to increase the rate of sterilization (higher humidity shortens the cycle dwell duration) and thereby improve the overall sterilization cycle time efficiency. After the dwell ends, the chamber is evacuated in preparation for another gas addition or for the final aeration with repeated evacuations and rinses with fresh air**.

* Humidified air is ambient air which is HEPA filtered before going into the humidification system. The humidification system creates water vapor using distilled water and an ultra sonic humidifier.

** Fresh air is ambient outside air passed through a HEPA Filter.

The critical parameters of the sterilization process are NO_2 concentration, relative humidity, duration of the NO_2 exposure dwell phase, and the number of exposure dwells (called pulses) that are repeated as part of the complete cycle. A cycle will have specified values for the NO_2 introduction, the humidity introduction, dwell duration and number of pulses. The cycle will also include a specific number of fresh air rinses as part of the aeration phase.

The NO_2 sterilant is distributed as a liquid in non-pressurized steel cylinders. The liquid NO_2 readily vaporizes into a gas under vacuum. Flow of the NO_2 sterilant from the cylinder to the sterilization chamber is accomplished through pressure differentials which in effect draw the NO_2 gas off the NO_2 in the cylinder. Delivery of the NO_2 sterilant is accomplished through software controlled opening and closing of valves along the gas path. Dosing is controlled with pressure transducers along the gas path and in the chamber.

The RTS 360 has a Windows-based computer as the controller. The control software is written in Visual Basic. The controller software executes predefined sterilization processes and monitors the state of the system during the idle periods. The sterilization processes and idle time processes are comprised of functions that include (but are not limited to):

- Evacuating and filling of the sterilizer
- Monitoring sensor outputs for indicating component status, including the door interlocks, NO_2 sensors and pressure transducers
- Controlling the amount of sterilant (i.e. the quantity of nitrogen dioxide (NO_2) and humid air) delivered to the sterilizer through opening and closing of valves based on software controls and pressure measurements.
- Monitoring system power status and cycle state
- Removing sterilant from the sterilization chamber
- Starting cycle phases at the appropriate time
- Controlling the number of rinses at the end of the sterilization
- Recording the session data in the computer, which permits retrieval at a later date
- Sending specified messages to the printer

The RTS 360 has been designed and developed following ISO 13485, ISO 14971, ISO 14937, IEC61010 and other regulatory standards

2. Equipment Description, Specification and Dimension of the R&D unit (trial)

Length:	78”
Width:	54” x 78”
Height:	78”
Weight:	3800 lbs.

Power requirements:	208 V – 230V, single phase 40 Amps, dedicated service Plug Type: NEMA 14-50P

3. Type and detail on emission control mechanism/device

Emissions are controlled by passing the evacuated gasses through a scrubber system containing commercial sodium permanganate chemical scrubber. The scrubber system consists of three primary scrubbers which operate in parallel and venting to a common line before passing through a secondary scrubber in series. The scrubber system is scaled to fully absorb all NO_2 on board the RTS 360 at any time. Scrubber replacement is a planned maintenance activity, timed to correspond to the changing of the sterilant cylinders.

Nitrogen dioxide is reduced to less than 1 ppm after passing through the scrubber system. Electrochemical sensors in the exhaust stream after the primary scrubbers and after the secondary scrubber cause alarming if the concentration NO_2 exceeds 1 ppm.

4. Maximum amount of NOx used in (a) R&D unit and (b) commercial unit

The amount of NO_2 used will depend on the concentration of NO_2 per pulse, the number of pulses per cycle, the number of cycles per week, and the number of weeks of operation per year.

The current estimated use for the R&D unit is 3.5 mg/L of NO_2 (in the fixed chamber volume of 730 L), 2 pulses per cycle, and 2 cycles per day operated 3 day a week and 50 weeks per year. This equates to 1.53 kilograms (3.38 lbs.) of NO_2 used per year

Noxilizer estimates that a typical commercial use will be 10 mg/L of NO_2, 4 pulses per cycle, 1 cycle per day operated 5 days per week and 50 weeks per year). This equates to 73 kilograms (161 lbs.) of NO_2 used per year.

The maximum use would be a continuous 24/7 operation, which is equivalent to 4 pulses per cycle, 12 cycles per day; 7 days per week and 52 weeks per year. At 10 mg/L, this equates to 911 kilograms (2008 lbs.) per year.

Keep in mind that this is NO_2 usage. The emissions after scrubbing are addressed next.

5. Estimate of NOx emission to the atmosphere - both trial and commercial unit (after scrubbing)

The scrubber system described above reduces the nitrogen oxide emissions to 1 ppm or less, regardless of the concentration of NO_2 in the chamber. Therefore the amount of NO_x emitted to the atmosphere will depend on the number of pulses per cycle and the number of cycles per week, and the number of weeks of operation per year.

For the Abbot Cardiovascular R&D use described above this equates to NOx emissions of 0.002 lbs. per year, for the typical commercial user this equates to 0.003 lbs. per year, and for continuous operation this equates to 0.054 lbs. per year.

6. Advantage of Noxilizer over EtO sterilization

The following table compares several aspects of NO_2 and EtO sterilization:

Attribute	NO_2	EtO
Sterilization Temperature	Room	Elevated (>35 C)
Concentration	3.5 – 20 mg/L	~600 mg/L
Cycle Time	80 – 120 min	Multiple Hours
Aeration Time	Included Above	Multiple Hours/Days
Materials Compatibility	Many Materials	Best in Class
Penetration of Container Material	Low	High
Residuals	Non-carcinogenic, Non-cytotoxic	Carcinogenic and Cytotoxic
Flammable?	No	Yes, Highly

The following table compares several chemical and safety aspects of NO_2 and EtO:

Safety-related Properties	NO_2	Hydrogen Peroxide	Ethylene Oxide
Color	Reddish-Brown	Colorless	Colorless
Odor Threshold	0.1 ppm	Odorless	200 – 400 ppm
OSHA PEL	5 ppm	1 ppm	1 ppm
NFPA: Health	3	3	3
NFPA: Flammability	0	0	4
NFPA: Instability	0	1	3

Operating Schedule – As amended in e-mail by Weyman Kam 3-30-15
8 pulses/cycle, 3 cycle/day, 20 days/month (480 pulses/mo)
Sterilizer Capacity - 730 Liter
NO_2 usage per Pulse - 20 mg/L

Max Daily Emissions - 8 pulses/cycle x 3 cycle/day x 20 mg/L/pulse x 730 L = 350,400 mg
0.3504 kg ➔ 0.77 lb/day
Monthly NO_2 Emissions – 480 pulses/mo x 20 mg/L/pulse x 730 L = 7,008,000 mg
= 7.008 kg/mo ➔15.4176 lb/mo
30-Day Average = 0.51392 lb (R1)

Per the manufacture, the emissions control system consists of 3 Primary Scrubbers operating in parallel and 1 Secondary Scrubber in series. Each of the Primary Scrubbers contains 3.6 kg of Purafil SP Media and the Secondary Scrubber contains a total of 2.0 kg. The Secondary Scrubber is constructed of two sections containing the Purafil SP Media (1 kg each) with the

void between the two sections containing an electrochemical sensor. The sensor is designed to trigger an alarm if the NO_2 concentration exceeds 1 ppm. The Purafil SP Media is designed to absorb a minimum of 31.85% of its weight in NO_2, see manufacturer's specs attached.

3 x (3.6 kg_{media}) x 31.85 $\%_{min}$ eff x 2.2 lb/kg = 7.56756 lb_{NO2} removed by Primary Scrubbers
2 x (1.0 kg_{media}) x 31.85 $\%_{min}$ eff x 2.2 lb/kg = 1.4014 lb_{NO2} removed by Secondary Scrubber
Total amount of NO_2 removed by control as designed = 8.96896 lbs

Manufacturer also states that the NO_2 will be supplied to Abbott in 2 lb cylinders and the Scrubber Media is scheduled to be completely changed out after every 2 cylinders of NO_2 used, after a total of 4 lbs. This practice will provide a safety margin of more than 100% of the absorption capacity remaining in the Media before complete replenishing of Purafil SP Media.

Conservative estimate of NO_2 emitted from the control is 0.5% of the NO_2 used. Scrubber media has a minimum control efficiency of 99.5%.

15.4176 lb_{NO2}/mo x 0.5% = 0.077 lb/mo ➔ 2.57 x 10^{-3} lb/day (to be used for NSR entry)

A more representative emission calculation assumes the maximum emission of 1 ppm_{NOx} for each of the pulses. This represents a maximum NOx emitted by the control of 480 ppm each month or less than 1.2 x 10^{-4} lb_{NO2}/mo ➔ 4.0 x 10^{-6} lb_{NO2}/day after control.

RULES COMPLIANCE

RULE 212: Public Notification
Paragraph 212 (c)(1) Requires a public notice for all new or modified permit units that may emit air contaminants located within 1,000 feet from the outer boundary of a school. Using estimations off of Google Maps Wild Roots Pre-School is 740 feet from Abbots' property line; however the Noxilizer will be housed in the G8 Lab which is about 1,300 feet from the Pre-School. A 30-Day Public Notice is not required under this paragraph.
Paragraph 212(c)(2) The equipment will not result in on-site emission increase exceeding the daily maximums as specified in the table in Rule 212(g). Therefore, a 30-day public notice period will not be required under this paragraph.
Paragraph 212(c)(3) Public notice will not be required under this paragraph. See Rule 1401 evaluation section.

RULE 401: Compliance is expected. Visible emissions are not expected from the proper operation of this equipment. There have been no visible emission citations at this facility.

RULE 402: Compliance is expected. Nuisance is not expected with the proper operation and maintenance of this sterilizer. There is no record of any nuisance complaints or citations issued to this facility.

REG XIII/XX: BACT not applicable, the maximum daily emissions before control is 0.77 lbs of NO_2. However, it is assumed that the 2-stage scrubber would be considered BACT for the Sterilizer.

Modeling is met. Emission rate for the Noxilizer is below the screening level of Table A-1 of Rule 1303.

Heat Input (mmBtu/hr)	NOx (lb/hr)
Non-combustion source	0.068
Noxilizer	<0.001

Offsets are not required. NOx is the only pollutant emitted. A conservative estimate of NOx emitted is less than 0.003 lb/day.

REG XIV: NOx is the only pollutant emitted by the Noxilizer. There are not Toxic Air Contaminants expected from this equipment.

REG XXX This facility is not in the RECLAIM program. The proposed project is considered a "de minimis significant permit revision" for non-RECLAIM pollutants and hazardous air pollutants (HAPs).

Non-RECLAIM Pollutants or HAPs

Rule 3000(b)(6) defines a "de minimis significant permit revision" as any Title V permit revision where the cumulative emission increases of non-RECLAIM pollutants or HAPs from these permit revisions during the term of the permit are not greater than any of the following emission threshold levels:

Air Contaminant	Daily Maximum (lbs/day)
HAP	30
VOC	30
NOx*	40
PM_{10}	30
SOx*	60
CO	220

* Not applicable if this is a RECLAIM pollutant

To determine if a project is considered as a "de minimis significant permit revision" for non-RECLAIM pollutants or HAPs, emission increases for non-RECLAIM pollutants or HAPs resulting from all permit revisions that are made after the issuance of the Title V renewal permit shall be accumulated and compared to the above threshold levels. This proposed project is the 2nd permit revision to the Title V renewal permit issued to this facility on January 11, 2012. The following table summarizes the cumulative emission increases resulting from all permit revisions since the Title V renewal permit was issued:

Revision	HAP	VOC	NOx*	PM_{10}	SOx	CO
1st Permit Revision: Spray Booth Installation	0	+0.367	0	+0.000706	0	0
2nd Permit Revision	0	0	+0.00257	0	0	0
Cumulative Total	0	+0.367	+0.00257	+0.000706	0	0
Maximum Daily	30	30	40*	30	60	220

* RECLAIM pollutant, not subject to emission accumulation requirements

RECOMMENDATION

Approve Permit to Construct for A/N 572699 as described in this report and the Facility Permit once it is off of 45-Day EPA notice.